



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY
MEETING AGENDA

April 12, 2007

Department of Health
Point Plaza East – Rooms 152-153
310 Israel Road
Tumwater WA 98501

CONVENE

Chair Rebecca Hille convened the meeting at 9:00 a.m. on April 12, 2007

Board Members present:

Gary Harris, RPh – Vice Chair
George Roe, RPh
Rebecca Hille, Chair
Rosemarie Duffy, RN
Susan Teil-Boyer, RPh
Vandana Slatter, PharmD
Dan Connolly, RPh

Staff Members present:

Lisa Salmi, Acting Executive Director
Tim Fuller, Pharmacy Consultant
Andy Mecca, Pharmacy Consultant
Grace Cheung, Chief Investigator
Jim Doll, Pharmacist Investigator
Joyce Roper, Assistant Attorney General
Doreen Beebe, Program Manager
Cheryl Christensen, Office Assistant 3

Guest present:

Andrew Bennett, WSU Pharmacist Extern
Andy Fernando, DOH Regulatory Affairs Manager
Karl Hohen, HPQA Legal Services Manager
Laurie Jenkins, Assistant Secretary
Bonnie King, HPQA Director

RULES HEARING DELIBERATIONS

The Board continued its deliberation regarding the proposed rules for Pharmacist's Professional Responsibilities **WAC 246-863-095** and Pharmacies' Responsibilities' **WAC 246-869-010**. The Board did not take public comments or answer questions from the audience during this agenda item.

Lisa Salmi provided background on the Board's activity to date regarding the proposed rules. She stated that the Board heard testimony from 91 stakeholders and the public at the rules hearing on March 29, 2007. Of the testimony, 46 supported the rules as written and 45 opposed. The intent of the proposed rules is to promote patient safety and access to health care by emphasizing pharmacist and pharmacies responsibilities. On March 30, the Board met and discussed the testimony and supporting documents. The Board directed staff to make changes to the Small Business Economic Impact Statement (SBEIS) and Significant Analysis (SA). Rebecca Hille read the vision and mission statements of the Board. The Board confirmed receipt and review of the revised SBEIS and SA. The Board confirmed receipt and review of all materials from the rules hearings. Board members Gary Harris and Vandana Slatter, who were not present during the hearing or deliberation on March 30, confirmed that they have reviewed all materials and have no questions at this time.

Tim Fuller summarized the changes made to the SBEIS, a directed by the Board. Mr. Fuller's presentation was followed by Andy Fernando's summary of changes to the Significant Analysis. Changes requested by the Board consisted of clarifying the explanation of potential costs and benefits in both documents.

Gary Harris confirmed, as stated in the SA, that "the rules are needed to minimize barriers to health care and to reduce risks for a patient's health when there may be an emergent need for a prescribed drug or device or a timely preventative use is essential to drug efficacy."

Madame Chair Hille asked if there is a consensus among the Board that the changes and information contained in the SBEIS and SA meet the direction of the Board. All agreed.

Following the approval of the SBEIS and the SA the Board was asked to discuss the proposed rule language.

Dan Connolly expressed the challenges and thoughtful work that went into crafting these rules, and acknowledges that it is difficult to craft rules that would satisfy all parties. He went on to state that the Board represents the people of the state of Washington and is charged with protecting their health and safety and ensure access to health care. The proposed rules will meet this requirement. George Roe concurred.

Vandana Slatter stated that this is a very complex issue and wished to acknowledge the compassion and commitment of the citizens of Washington in their active participation/interest in their health care.

Susan Teil Boyer acknowledges that it has been a difficult process, but also felt the proposed rules were well crafted and protecting patients is what the Board does. Ms. Teil-Boyer stated that the first line of WAC 246-869-095 is the key statement “a pharmacist’s primary responsibility is to ensure patients receive safe and appropriate medication therapy.” She stated that pharmacists will need to adjust to this rule.

Gary Harris stated that the Board members have read a tremendous amount of information and stakeholder input over the past sixteen months related to these rules. Mr. Harris declared that the Board has made a good effort to draft the best rule it can.

Mr. Harris also stated that it is not the intent of the Board or the rule to expect every pharmacy to stock every drug, in every strength, for every medical condition. There are many options available in this new rule that would allow a pharmacist to provide service to patients.

Rosemarie Duffy also acknowledged how challenging this process was and commended the Board for its professionalism and staff for their work.

ACTION: Gary Harris moved that the Board accept **WAC 246-863-095** Pharmacist’s Professional Responsibilities as it is currently amended. George Roe second. **MOTION CARRIED 6-0.**

ACTION: George Roe moved that the Board accept **WAC 246-869-010** Pharmacies Responsibilities. Vandana Slatter second. **MOTION CARRIED 6-0.**

The adopted rules will become effective 31 days after filing with the Code Reviser’s office. The anticipated effective date is mid-June and all interested parties will be notified.

CONSENT AGENDA

- 1.2 Pharmacy & Other Firm Application Approval
 - Pharmaceutical Firms – New and Closed 2/11/07-3/13/07
- 1.4 Pharmacy Tech Training Program Approval
 - Lake Chelan Community Hospital
 - Coulee Community Hospital
 - TLC Integrative Pharmacy
 - Republic Drug Store
 - Shiraz Specialty Pharmacy
 - Toledo Pharmacy
 - University of Medicine of Pharmacy Bucuresti Romania – Ionela Todoran
 - Apollo College - Bosie ID – Jennifer Bengner
 - Western Career College – Emeryville CA – Maninder Kaur
 - Allied College – St Louis MO – Melissa Fagan
 - University of Montana-Missoula – Shannon Beadle
 - San Antonio College of Medical & Dental Assistants – San Antonio TX –Rebecca Ortiz
 - San Joaquin Valley College – Visalia CA – Ronald K. Johnson

- United Education Institute – San Diego CA – Joseph G. Quintella
 - Pines City Colleges – Baguio City Philippines - Vanelli G. Ignacio
- 1.5 Collaborative Drug Therapy Agreement Acceptance
- Inpatient Medication – Virginia Mason – Various
 - Anticoagulation – Cascade Valley Hospital/Clinics - Various
 - Refills/Initiating or Continuing Drug Therapy – Community Health Centers Snohomish County – Various
- 1.8 Board Minute Approval – March 1, 2007

Items 1.1 – Pharmacist License Application Approval; 1.3 – Pharmacy Technician Application Approval; 1.6 – Automated Drug Dispensing Device Acceptance; and 1.7 – Sample Distribution Requests were deleted from the consent agenda. **ACTION:** George Roe moved that the Board approve 1.2, 1.4, 1.5, and 1.8 of the consent agenda. Susan Teil-Boyer second. **MOTION CARRIED 6-0.**

REPORTS

Acting Executive Director

Lisa Salmi reported:

- Performance Auditors continue to meet with credentialing and investigative staff and we expect they will be in the building through April. The final report to the legislature is due in July.
- Staff continues to serve on committees to plan for the conversion to the new licensing program, eLicense. Doreen Beebe and Janelle Teachman participated in intensive training on the system in March. They will serve as trainers for staff members. The implementation date of the new licensing program is February 2008.
- Grace Cheung and Ms. Salmi are participating in the HSQA Organization Review workgroups -Inspection and Compliance Workgroup and Customer Service Workgroup, respectively. Judy Haenke, Program Manager for the Veterinary and Optometry Boards, is on the Health Professions and Facilities Workgroup.
- The Food and Drug Administration recently visited several compounding pharmacies in the state to request voluntary samples of compounded products. The products will be tested for sterility and to analyze the contents. We have heard that Senator Kennedy is working on a bill to bring compounded products under stronger regulation by the FDA and add limits to their distribution. State pharmacy boards currently regulate compounding pharmacies at the state level. Under Senator Kennedy's proposal, primary oversight for compounded products would shift to the FDA.
- Quarterly Investigator meeting was held on March 7-8. Susan Teil-Boyer represented the Board at these meetings.
- The waiver request to DEA asking permission for the PH:ARM pilot project to collect controlled substances was sent in March. The waiver request received support from numerous state and private agencies including the Governor, Attorney General, Mary Selecky and the Department of Ecology. To date, there have been 2 incinerations.
- The Department has granted the Board authorization to purchase new computers for field investigators.

- Met with representatives of the DOH Trauma Program to prepare for a briefing to Mary Selecky on strategies to reduce poisoning deaths in Washington State. Washington State is seeing an epidemic of poisoning deaths from unintentional drug overdoses. The high risk groups include males 35-45 years of age. Washington State data and national data suggest the increase is due to intentional abuse of prescription drugs, especially pain medications.
- Tim Fuller and Ms. Salmi will meet with representatives of Facilities Services and Licensing and the Executive Director of the program that administers the Health Care Assistance Program to discuss issues concerning the scope of practice of Health Care Assistants. Currently, HCA are only allowed to administer injectable drugs (e.g., vaccines and numerous other injectable meds); but not the oral ancillary medications ordered by the provider (e.g., the Tylenol that goes with the vaccination). A Seattle hospital has asked the Department to grant an exemption to allow Health Care Assistants to administer oral meds as well.
- Stakeholder work will begin soon on establishing rules for pharmaceutical services in correctional facilities.
- Currently recruiting for four positions; credentialing manager, support staff for discipline, pharmacy investigator, and the Executive Director. The application deadline for the Executive Director position is April 30th.
- The NABP Annual Meeting will be held May 19-22 in Portland, Oregon. Susan Teil-Boyer, Gary Harris, Rebecca Hille and George Roe will represent the Board. Doreen Beebe, the investigative staff and Ms. Salmi will also attend.
- Tim Fuller, Jim Doll and Ms. Salmi will be participating in this year's Strategic National Stockpile Reception Storage and Staging annual full-scale exercise (WASABE 9 – 2007) on October 30th in Spokane.
- Upcoming meetings: HPQA Annual Leadership Conference - May 14, Radisson Hotel in Seattle; HPQA Annual Board/Commission and Committee Conference – September 27-28, Renton Holiday Inn in Renton; Citizen Advocacy Center Meeting – October 31-November 2, Edgewater Hotel in Seattle.

Board Member Reports:

George Roe accompanied Jim Doll on an inspection of the Yakima Valley Farm Workers Clinic – Call center. (Representatives of YVFWC were unable to attend. – this agenda report has been deferred to a future meeting.)

Commented on the Washington State Pharmacy Association's webpage encouraging patients to take an active role in their health care by helping their physicians and pharmacists to prevent medication errors by carrying a list of their medications and to question anything if it doesn't appear right.

Susan Teil-Boyer spoke briefly about medication reconciliations – a new requirement by the Joint Commission on Accreditation of Health Care Organizations and Hospitals.

Ms. Teil-Boyer attended the quarterly Investigators' Meeting held in March. She congratulated the Investigators and the Chief Investigator for their great work!

Gary Harris commented on the March 1 stakeholder meeting regarding SOMA and his role as Board sponsor.

Assistant Attorney General

Joyce Roper updated the status of the Ongom Case regarding the standard of evidence in health practitioners' disciplinary cases. A petition for review of the Washington's court ruling has been filed with the US Supreme Court. The Association of Nursing Boards and a patient advocacy group have signed on to the petition as amicus curiae (friends of the court) which may increase the chances the court will review the lower court's ruling. The Federation of State Medical Boards and CLEAR may sign onto the petition as well. Deadline for amicus curiae petitions is April 18th.

Consultant/Investigator Pharmacists

Andy Mecca reported:

- Activities of Washington State University Pharmacy Extern Andrew Bennett. Mr. Bennett is in his third week and has been in the field conducting inspections, case management team meetings and various other functions.
- Mr. Mecca will be holding an electronic stakeholder comment period regarding the petition for rulemaking requesting the placement of carisoprodol in schedule IV of the Uniformed Controlled Substance Act. He will update the Board on the comments received at the May meeting.
- Attended the Washington State Patient Safety Coalition Conference held at SeaTac on March 22nd. The keynote speaker was Don Berwick, the co-founder and CEO of the Institute for Healthcare Improvement, which has the "5 Million Lives" campaign. Topics included patient's perspective of medication errors, systems approach to medication error, etc. On April 5th attended a meeting regarding the Opioid Guidelines for chronic and ongoing pain management. Guidelines are written and they are starting an educational pilot program to get information out.

Tim Fuller reported:

- He confirmed with Buck Stevens of PDX-Rx systems that faxing a copy of the original prescription will meet the Board's intent that the central fill final check pharmacist has the ability to view an image of the prescription.
- Mr. Fuller indicated that the Emergency Response Strategic National Stockpile is planning its first full scale exercise to be held in Eastern Washington in Spokane. He acknowledged that there will be challenges in terms of logistics and recruiting volunteers.
- Mr. Fuller shared that he recently visited the Bellegrove/Stilligumish tribe telepharmacy operation. He indicated that the video transmission satellite systems they were using is inadequate and will provide follow-up to the Board at a future meeting.

Chief Investigator

Grace Cheung distributed copies of the Chief Investigator's report which highlighted investigations and inspections for the month of February. Ms. Cheung also briefed the Board on the failed recruitment efforts for the Central Washington Investigator. Staff has broadened the recruitment efforts by posted notices in the Spokesman Review. The Board asked if part-time or job sharing should be considered.

- Tim Fuller, Andy Mecca, Dick Morrison and Kelly McLean assisted with the Pharm 440 class at the University of Washington. Pharm 440 focuses on how communication influences the pharmacist's activities in designing, delivering, and managing patient-focused pharmaceutical care e.g. smoking cessation programs.
- On March 10th, Stan Jeppesen and Andy Mecca will help out with the UW Law Class. Staff is conducting a law book index review for the development of an electronic law book (CD).
- Investigator's Meetings
 June 6/7 – Dan Connolly
 September 12/13 – George Roe
 December 5/6 – Vandana Slatter
- Due to workload challenges Board Investigators will decline doing the Consumer Safety Product inspections.
- Ms. Cheung acknowledged Lisa Salmi for negotiating funds for new equipment for the investigators and approval to attend the NABP annual conference.

Program Manager

Doreen Beebe reported:

- Attended “Train the Trainer” training the 3rd week of March for eLicensing. The implementation is planned for early 2008 and will show multiple credentials on one screen. It should be helpful with our restructure.
- The Office Assistant 3 position has been filled by Cheryl Christensen, who transferred from the Department of Social and Health Services.

EXECUTIVE SESSION

The Board adjourned at 12:00 p.m. for the Executive Session to discuss personnel issues and pending litigation.

The Board reconvened at 1:05 p.m. for Presentations and Discussions.

PRESENTATIONS

Presentation of the Secretary of Health's Sanction Guidelines. PowerPoint and handouts facilitated by Karl Hoehn, Health Prof Sec 2, HSQA. Mr. Hoehn indicated that the Secretary adopted the guidelines on May 31, 2006 for use in the professions she regulates. Mr. Hoehn stated public protection is paramount consideration for the guidelines which provide framework for discipline with consistency and ensures connection between the conduct and sanction. The guidelines involve 5 steps which include 7 categories of conduct. If more than one conduct is under review, they are prioritized with the additional charges as aggravating. We are largely compliant with the guidelines already. **ACTION:** Vandana Slatter moved that the Board adopt the guidelines with the understanding that it is still in the development process. Dan Connolly second. **MOTION CARRIED 6-0.**

Board Goals – 2007/2009. Tim Fuller provided an overview of the Current Rules Workload.

- **Complete Rule Process for the Top Five Rule Priorities**
 - Correctional Facilities – stakeholder meetings should begin to occur within the next 6 weeks
 - Pharmacy Technician National Standardized Examination – will need to revamp the technician education. Susan Teil-Boyer and Rosemarie Duffy volunteered themselves as sponsors.
 - Precursor Suspicious Transaction – has been pushed back to July 2007.
 - Add SOMA to CSA – the next step is electronic stakeholder meetings and will report back at next Board meeting.
 - Update Wholesaler Rules – the regulations need to be looked at and may require legislation. Per Andy Mecca, with SOMA and Correctional Facilities, probably fall at the earliest (or early next year). Pedigree – need AAG opinion on whether we have authority to require electronic pedigree -- (federal – authorized distributor of record – other areas in our regulations that needs to be further flushed out – security, storage etc).
 - Update Animal Control Agency and Humane Society Rules – Doreen Beebe stated the guidelines have been drafted but have not been distributed to stakeholders yet. There will be a review in July 2007.
- **Increase Communication & Awareness to the Profession and Public**
 - Acknowledge Board's Accomplishments
 - Communicate Board's Mission & Vision
 - "Frequently Asked Questions"
 - For Public Safety Retaining Pharmacist Investigators
- **Establish Continuing Education Credit for Attending Board Meetings**
- **Communicate Information via Email to Washington Pharmacists**

Reorganization/Restructure. Laurie Jenkins, Assistant Secretary of Health Systems Quality Assurance, distributed a current organizational chart which includes the following offices:

- Facilities and Services Licensing – over 7,000 facilities
- Emergency Medical Services & Trauma System – Access to Trauma care – system throughout the state of Washington and injury prevention
- Community and Rural Health – recruit Healthcare practitioners in rural areas – hospitals
- Health Professions Quality Assurance – Health Professions 57 professions – regulated by DOH or in combination with Boards and Commissions – 2007 Legislation will create 3 new professions

Ms. Jenkins continued to explain that in December 2005 the division undertook a Strategic Plan to address concerns by the public and legislators on how responsive we are and if we are structured in a way best to ensure safe and appropriate healthcare; and improving public confidence. The plan's priorities are:

- The development of a single complaint process
- Establishing common business practices throughout the department

- Enhancing data management
- Utilizing technology and enhancing/updating our data and systems
- Improving workforce diversity, competency and satisfaction

Under the Office of the Assistant Secretary, five new functional offices have been proposed:

- Inspection and Compliance – to include investigators and inspectors for more consistency and a systems based approach to workload management
- Legal Services – won't change very much, remain similar to current
- Customer Service – initial point of contact public/credential holder contact.
- Community Health Systems – to include EMS & Trauma and Community and Rural Health - Office designed to link communities with the health care they need, ensuring access.
- Health Professions and Facilities – Support for Boards and Commissions, rules development and education of practitioners – prevention oriented.

The Office of the Assistant Secretary anticipates additions of a Human Resource Workforce Analyst and Communications Consultant. Anticipated implementation in the Fall 2007.

Board members expressed their belief that maintaining expertise in the field investigators is critical in achieving the goals of the Board through inspections, investigations and providing technical assistance to the profession.

Ms. Jenkins indicated that she would not anticipate that non-pharmacists would be doing inspections or pharmacy related investigations unless appropriate. Ms. Jenkins invited Board members to either call or email her if they have any questions. She also mentioned the RIP (Rumors In Progress) page on the DOH website; which is updated weekly in efforts to keep lines of communication open and transparent.

Bonnie King, Director of Health Professions Quality Assurance, provided an update on the recruitment for the Executive Director position for HPS4. The recruitment closes on April 30th and interviews will be conducted mid-May. The Board will be involved in the interview process and must confirm the Secretary's selection. Ms. King complimented Lisa Salmi on her role as Acting Executive Director.

DISCUSSION

2007 Legislation Update

Lisa Salmi reported:

- *ESSB 6032 Medical use of marijuana* - this bill looks like it will pass. The department will have to adopt the new rules by January 1, 2008. The bill allows patients to have a 60 day supply and helps to ensure that the marijuana is received from a safe, consistent source. However, marijuana obtained under this bill is still federally illegal.
- *SHB1553 - Prescription Monitoring Program* –this bill has died but the PMP program has been added to the Blue Ribbon Commission bill, which is still alive, but has transfers

the program back and forth from the Washington State Health Care Authority to the Board of Pharmacy.

- *2SHB1103* –contains language transferring the authority to investigate to the Secretary – this bill has died.
- *SHB1300 Agency Request Legislation* – appears to still be alive; 2 other bills have been added.
- *EBB1667 – Health Professions Licensing Fees* – this bill has changed multiple times. It calls for a three tier fee structure based on the type of credential - license/registration/certification.
- HB1331/SB5485/SSB5485 - Vet technician
- New Professions – Animal massage practitioner, Dental Assistants Registration, Athletic Trainers, and Physical Therapy Assistants

Presentation of Agreed Orders

Business Meeting Adjourned

There being no further business, the Board adjourned at 4:05 p.m. The Board of Pharmacy will meet again on May 17 – 18 in Vancouver, Washington.

Respectfully Submitted by:

Cheryl Christensen, Board Staff

Approved on May 17, 2007

*Rebecca Hille, Chair
Board of Pharmacy*